

C2

25. (Amended) A method of making a food composition for use as a dietary supplement comprising the steps of:

providing a supply of propionibacteria;
selecting an amount of propionibacteria sufficient to release physiologically significant amounts of nitric oxide into the human and digestive tract;
providing a food product selected from a list including cheese, sources of dietary fibre, fermented milk, dessert cream, cake, and tonic drink; and
adding said propionibacteria to said food product.

REMARKS

Claims 13-16, 19-21, 24-26, 29, and 30 are at issue. Claims 17, 18, 22, 23, 27, 28, 31, and 32 have been canceled. No claims have been allowed.

1. Claim Rejections -35 U.S.C. § 112

Applicants respectfully submit that Claims 17, 18, 22, and 23 have been canceled.

2. Claim Rejections- 35 U.S.C. § 102(b)

The Examiner has rejected Claims 13-16, 19-21, 24-26, 29, and 30 as being anticipated by U.S. Patent No. 4,379,170 to Hettinga et al. In the Final Office Action, the Examiner indicates that the "cited bacteria belong to the same bacterial genus and they are used for the same purpose of preparing dietary composition [sic] such as cheese." (Final Office Action, page 5).

U.S. Patent No. 4,379,170 to Hettinga et al. discloses, in pertinent part, a process for the manufacture of a Swiss or Emmental flavored cheese product in which a mixture containing skim milk is fermented with 80 ppm of Rhozyme P-11 and 6.6% inoculum of a 50/50 mixture of Propionibacteria P16 and P20 (G-broth, 6.2×10^9 cells per gram of P16, 1.2×10^9 cells per gram of P20) for 5 hours. This mixture is combined with a pasteurized skim milk concentrate and pasteurized cream, and then undergoes a cooking process.

Claim 13 calls for a composition for use as a dietary supplement for human and animal consumption which comprises more than 10^9 cells/gram of propionibacteria, and is capable of releasing a physiologically significant amount of nitric oxide into the human and animal digestive tract.

Claim 19 calls for a composition for use as a dietary supplement comprising a sufficient quantity of propionibacteria and one or more selected from the group consisting of bifidobacteria and lactic acid bacteria. The composition is capable of releasing a physiologically significant amount of nitric oxide into the human and animal digestive tract.

Claim 20 calls for a method of making a composition for use as a dietary supplement which comprises the steps of providing a supply of propionibacteria and selecting an amount of propionibacteria sufficient to release physiologically significant amounts of nitric oxide into the human and animal digestive tract.

Claim 25 calls for a method of making a food composition for use as a dietary supplement which comprises the steps of providing a supply of propionibacteria; selecting an amount of propionibacteria sufficient to release physiologically significant amounts of nitric oxide into the human and animal digestive tract; providing a food product selected from a list including cheese, sources of dietary fibre, fermented milk, dessert cream, cake, and tonic drink; and adding the propionibacteria to the selected food product.

Claim 29 calls for a method of making a composition for use as a dietary supplement which comprises the steps of providing a supply of propionibacteria and at least one of the group consisting of bifidobacteria and lactic acid bacteria, and selecting an amount of propionibacteria sufficient to release physiologically significant amounts of nitric oxide into the human and animal digestive tract.

*the same
is claimed* [Applicants respectfully submit that Hettinga et al. discloses the utilization of propionibacteria for the purpose of *making* cheese. Applicants submit that in all likelihood, the finished cheese product disclosed in Hettinga et al. does not contain live cultures of propionibacteria. Moreover, Applicants respectfully submit that Hettinga et al. does not suggest that live cultures of propionibacteria are resident in the final cheese product. In fact,

at columns 9-10, under the heading "Example 2," Hettinga et al. discloses an analysis of the fermentate and skim milk concentrate/cream mixture. Applicants submit that no mention is made of any live cultures of propionibacteria. Applicants further submit that there is nothing in Hettinga et al. to suggest that, even in the event that some live cultures of the propionibacteria survive the cheese making process, those remaining live cultures would be present in an amount capable of releasing a physiologically significant amount of nitric oxide in the human or animal digestive tract, as called for in independent Claims 13, 19, 20, 25, and 29.

*at least
enzymatic
active
since
fermentation
is disclosed*

In response to the Examiner's 35 U.S.C. § 102 (b) rejection, Applicants respectfully remind the Examiner that "[a] rejection for anticipation under § 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference." In re Paulsen, 30 F.3d 1475, 1478 (Fed. Cir. 1994). In light of the foregoing, Applicants respectfully submit that because Hettinga et al. does not disclose a composition having an amount of propionibacteria capable of releasing a physiologically significant amount of nitric oxide into the human or animal digestive tract, as called for by independent Claims 13, 19, 20, 25, and 29, Hettinga et al. does not teach every element of the claimed invention. Therefore, Claims 13, 19, 20, 25, and 29, and those claims dependent thereon, are neither anticipated nor rendered obvious by Hettinga et al.

*Same
bacterium
P20
in the
same
anterior
10⁹*

The Examiner has rejected Claims 13-18 and 20-28 as being anticipated by U.S. Patent No. 5,573,947 to Madec et al.

U.S. Patent No. 5,573,947 to Madec et al. discloses the use of a selective culture medium which permits the *counting* of propionic bacteria under anaerobic conditions.

Similarly to Hettinga et al., Madec et al. does not disclose a composition for use as a dietary supplement containing an amount of propionibacteria capable of releasing physiologically significant amounts of nitric oxide into the human and animal digestive tract. Applicants respectfully submit that although Madec et al. does mention some of the known uses for propionibacteria, for example in the production of certain types of cheese, such disclosure is merely for the purpose of demonstrating the usefulness of Madec et al.'s

counting invention. Applicants respectfully submit that Madec et al. does not disclose or suggest a dietary supplement containing an amount of propionibacteria capable of releasing a physiologically significant of nitric oxide into the human or animal digestive tract. Applicants respectfully submit that independent Claims 13, 20, and 25, and those claims dependent thereon, are not anticipated or rendered obvious by Madec et al.

3. Claim Rejections- 35 U.S.C. § 103(a)

The Examiner has rejected Claims 13-32 as being unpatentable over U.S. Patent No. 4,379,170 to Hettinga et al., taken with U.S. Patent No. 5,573,947 to Madec et al. and Balows et al. Applicants have canceled Claims 17, 18, 22, and 23.

Hettinga et al. and Madec et al. are discussed hereinabove.

Balows et al. (page 556, 2nd paragraph) discusses generally that certain propionic bacterium have been found to participate in nitrate reducing activity and may induce denitrification processes. Additionally, Balows et al. discloses that certain propionic bacteria are capable of reducing nitrates into gaseous products.

Applicant respectfully submits that Balows et al. fails to cure the defects of Hettinga et al. and Madec et al. Moreover, Balows et al. contains no suggestion, teaching, or motivation to combine Hettinga et al. and Madec et al. to render obvious the claimed invention.

In response to the Examiner's § 103(a) rejection, Applicants respectfully remind the Examiner of the non-obviousness standard set forth in 35 U.S.C. § 103 (a), which provides that an invention is not patentable if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." Furthermore, a "[d]etermination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention." ATD Corp. v. Lydall, Inc., 159 F.3d 534, 546, 48 U.S.P.Q.2d 1321, 1329 (Fed. Cir. 1998). Rather, prior art references are properly combined

only where there is a suggestion, teaching, or motivation to combine them, and that suggestion, teaching, or motivation comes from the prior art references themselves. C.R. Bard, Inc. v. M3 Systems, Inc., 157 F.3d 1340, 1352, 48 U.S.P.Q.2d 1225, 1232 (Fed. Cir. 1998).

Because the suggestion, teaching, or motivation to combine references must come from within the references themselves, and the cited references do not contain such a suggestion, teaching, or motivation, Claims 13, 19, 20, 25, and 29, and those claims dependent thereon, are not rendered obvious over Hettinga et al., taken with Madec et al. and Balows et al. Moreover, even if the teachings of Balows et al., Hettinga et al., and Madec et al. are combined, they do not disclose a composition for use as a dietary supplement having an amount of propionibacteria capable of releasing a physiologically significant amount of nitric oxide into the human and animal digestive tract.

In view of the foregoing, Applicants submit that all claims are in condition for allowance. Should any questions concerning any of the foregoing arise, the Examiner is invited to telephone the undersigned at (219) 460-1695.

[THIS SPACE INTENTIONALLY LEFT BLANK]

PATENT
HER0033

In the event the Applicants have overlooked the need for an extension of time, an additional extension of time, or payment of fee or additional payment of fee, Applicants hereby petition therefore and authorize any charges be made to Deposit Account No. 02-0385, Baker & Daniels.

Respectfully submitted,

Anthony Niewyk
Registration No. 24,871
Attorney for Applicants

BAKER & DANIELS
111 East Wayne Street
Suite 800
Fort Wayne, IN 46802
Telephone: 219-424-8000
Facsimile: 219-460-1700

Encs. - Attachment I
Return Postcard

CERTIFICATE OF MAILING
I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: ASSISTANT COMMISSIONER FOR PATENTS, WASHINGTON, DC 20231, on May 7, 2001.

Anthony Niewyk, Reg. No. 24,871
NAME OF REGISTERED REPRESENTATIVE

SIGNATURE

May 7, 2001

ATTACHMENT I

15. (Amended) The [A food product including a] composition according to Claim 13, wherein said [food product is] composition is added to a food product selected from [the] a list [of cheeses] including cheese, sources of dietary fibre, fermented milk, dessert cream, cake, and tonic drink.

25. (Amended) A method of making a food composition for use as a dietary supplement comprising the steps of:
 providing a supply of propionibacteria;
 selecting an amount of propionibacteria sufficient to release physiologically significant amounts of nitric oxide into the human and digestive tract; [and]
 providing a food product selected from [the] a list [of cheeses] including cheese, sources of dietary fibre, fermented milk, dessert cream, cake, and tonic drink; and
 adding said propionibacteria to [a] said food product [selected from the list of cheeses, sources of dietary fibre, fermented milk, dessert cream, cake, and tonic drink].